

REMARKS

In the Office Action dated February 5, 2009, claims 1, 2, 4, 9, 10, 12 and 15-19, in the above-identified U.S. patent application were rejected. Reconsideration of the rejection is respectfully requested in view of the above amendments and the following remarks. Claims 1, 2, 4, 9-10, 12 and 15-19 remain in this application and claims 3, 5-8, 11 and 13-14 have been canceled.

In the only remaining rejection, claims 1, 2, 4, 9, 10, 12 and 15-19 were rejected under 35 USC §103(a) as unpatentable over Bleumer in view of Pavone. The office action contends that the language "comprising" and "consisting essentially of" are interpreted as encompassing additional active ingredients such as IL-2 as disclosed in the prior art. The claims have been amended to indicate that the G250 antibody or fragment thereof and said IFN- α are the only active ingredients which are administered or that IFN- α is the only cytokine which is administered. This language clearly excludes the administration of IL-2 in combination with G250 and IFN- α as disclosed in the cited prior art. This amendment is supported by the examples in the present application and the general disclosure which indicates that a low dose cytokine is administered. The present application does not indicate that more than one cytokine can be administered and indicates that higher doses can cause cytokine related toxicity. Applicants contend that even if Pavone did teach a combination of IL2 and IFN- α for the treatment of RCC (which Pavone does not), combining Pavone and Bleumer would result in a composition comprising G250 antibody, recombinant IFN- α in a low dose form and recombinant IL-2 in a low dose form. Since Pavone does not provide any indication that the described immunological effect would also be achieved by single administration of

recombinant IFN- α in a low dose form (i.e. without additionally administering recombinant IL-2 in a low dose form), a person skilled in the art cannot arrive at a method for treating RCC comprising co-administering G250 antibody and IFN- α as the only active ingredients, as required by the present invention. The present situation is different from *In re Kerkhoven* as discussed in the previous office action. In the present situation, the active ingredients of the two references are not simply added together to arrive at the present invention. In order to arrive at the present invention, one skilled in the art would need to combine the active ingredients in Bleumer and Pavone and then delete recombinant IL-2 from the combination. Since there is no suggestion in either of these references that the recombinant IL-2 is unnecessary, such a combination is based on inadmissible hindsight. In view of the above discussion, applicants contend that one skilled in the art would not combine Bleumer and Pavone to arrive at the present invention and request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 1, 2, 4, 9-10, 12 and 15-19 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper. may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

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